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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/995,938	11/27/2001	Joanne Chory	SALKINS.046A	2882

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EXAMINER	
BAUM, STUART F	

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 09/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/995,938	CHORY ET AL.	
	Examiner	Art Unit	
	Stuart F. Baum	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 June 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23,25 and 26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *25 and 26* is/are allowed.

6)☒ Claim(s) *1-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The amendment filed 6/17/2004 has been entered.

2. Claims 1-23 and 25-26 are pending and examined in the present office action.

Claims 24 and 27 have been canceled.

3. Rejections and objections not set forth below are withdrawn.

4. The text of those sections of Title 35, U.S. Code not included in this office action can be found in a prior office action.

Written Description

5. Claims 1-6, 8-12, and 15-21 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is maintained for the reasons of record set forth in the Official action mailed 2/17/2004. Applicant's arguments filed 6/17/2004 have been fully considered but they are not persuasive.

Applicants contend that the specification provides ample information to fulfill the written description requirement. Applicants contend that the specification provides more information than is provided in the "Synopsis of application of written description guidelines" published by the USPTO. Applicants refer to Example 9, pages 35-37 of the "guidelines" which covers claims drawn to nucleic acids isolated by hybridization techniques. Applicants contend that whereas the "synopsis example" discloses a single cDNA, Applicants disclose four cDNAs, all of which have the claimed function -- producing a genetically modified plant having increased size as compared to a wild-type plant. Applicants contend that the claims are drawn to a genus

of nucleic acids all of which must encode a polypeptide with an amino acid sequence at least 80% identical to SEQ ID NO:6 and must encode a protein with a specific activity. Applicants contend that the four disclosed cDNAs adequately describe a genus of cDNAs, and as such, Applicants are in possession of the claimed invention (paragraph bridging pages 10 to 11 of response).

The Office contends that Applicants fact pattern is not congruent with Example 9 of the "written description guidelines". Example 9 discloses a cDNA sequence whose complement was used as a probe to isolate another nucleic acid sequence encoding a protein with the same function as the initial cDNA, i.e., it binds to a dopamine receptor and stimulates adenylate cyclase activity. This is a very specific biochemical function. Applicants' cDNAs were isolated in a mutagenesis experiment in which plants were selected that did not respond to brassinazole, a triazole-type brassinosteroid biosynthesis inhibitor (see page 34, Example 3, of the specification). Applicants do not disclose a specific molecular function for the isolated cDNA, other than when overexpressed in a plant, cause the plant to exhibit increased cell elongation (see pages 37 and 38, Example 8 and Table 2). Applicants do not disclose the identity of the isolated cDNAs nor if all the cDNAs encode proteins with identical biochemical functions. For claims drawn to sequences that exhibit less than 100% sequence identity to SEQ ID NO:6, Applicants have not included a limitation that specifies that the encoded protein has a specific biochemical function, and as such, the fact pattern for Applicants' claims is not identical to Example 9 of the written description guidelines. Applicant is reminded that a biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic

for written description purposes, even when accompanied by a method of obtaining the claimed sequence. Given the lack of disclosed information, Applicants have not fulfilled the written description requirement for the broadly claimed invention.

Scope of Enablement

6. Claims 1-23 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a nucleic acid molecule comprising a nucleotide sequence encoding the bzr1-D polypeptide of SEQ ID NO:7, a nucleic acid molecule of SEQ ID NO:2, a method of producing a genetically modified plant having increased size as compared to a wild-type plant, a genetically modified plant exhibiting increased size in comparison to a wild-type plant, or a genetically modified seed that produces a plant with increased size in comparison to a wild-type plant comprising transforming a plant with a nucleic acid encoding SEQ ID NO:7 or wherein the nucleic acid sequence is set forth in SEQ ID NO:2, does not reasonably provide enablement for claims drawn to a method of producing a genetically modified plant having increased size compared to a wild-type plant, a genetically modified plant exhibiting increased size in comparison to a wild-type plant, or a genetically modified seed that produces a plant with increased size in comparison to a wild-type plant comprising transforming a plant with a nucleic acid encoding a polypeptide comprising an amino acid sequence exhibiting at least 80%, 85%, 90% or 95% sequence identity to SEQ ID NO:6 or wherein the nucleic acid molecule is SEQ ID NO:1 or wherein the nucleic acid molecule encodes a polypeptide of SEQ ID NO:6. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these

claims. This rejection is maintained for the reasons of record set forth in the Official action mailed 2/17/2004. Applicant's arguments filed 6/17/2004 have been fully considered but they are not persuasive.

Applicants contend that the claimed invention is enabled as evidenced by a parsed analysis of the eight *Wands* factors. Applicants contend that the quantity of experimentation is not undue. The molecular biology techniques for generating vectors, transformed plants, and screening for enlarged plants are routine (page 12, top paragraph).

The Office contends that the individual steps, i.e., generating vectors, transformed plants and screening for enlarged plants, is routine, assuming that one skilled in the art is working with one sequence. Combining all the individual steps and taking into account the lack of guidance and/or examples in using non-exemplified nucleic acid sequences produces undue trial and error experimentation for making the broadly claimed invention.

Applicants contend that the specification discloses working examples and that methods of alignment are discussed. Such alignments will provide elements that "are likely required" for function and will indicate some of the mutations that may be accommodated without affecting the function (page 12, 2nd paragraph).

Applicants' claims are drawn to sequences from all organisms but Applicants only disclose sequences from Arabidopsis. For the alignment to reflect conserved domains for the claimed genus, sequences from other species of plants and even other organisms would be required.

Applicants contend that working examples are provided. Applicants contend that three nucleic acid molecules encoding polypeptides that exhibit at least 80% sequence identity to SEQ ID NO:6 is provided in Example 8 on page 37, lines 21-22 (page 12 last paragraph).

The Office contends that Applicants' specification discloses that overexpression of BRZ1 and BRZ2, which exhibit at least 80% sequence identity to SEQ ID NO:6, did not cause any change to plant development when overexpressed in a plant. On page 38, Table 2, Applicants report that overexpression of wild-type BRZ1 or BRZ2 had "no effect" on the phenotype of transformed plants. On page 37, last paragraph, Applicants state "Expression of wild-type BZR1 and BZR2 genes from their own promoters did not cause obvious phenotypes. BRZ1 and BRZ2 exhibit at least 80% sequence identity to SEQ ID NO:6 and yet they do not produce the claimed result. Therefore, given the unpredictability of transforming a plant with a nucleic acid encoding BRZ1 or BRZ2, undue trial and error experimentation would be required by one skilled in the art to make and/or use the claimed invention.

Applicants contend that making and using the invention requires only routine techniques and is a matter of routine testing of sequences related to those disclosed (page 13, 1st full paragraph).

The Office contends that although the biotech methods are known, undue experimentation would be required to screen through DNAs encompassed by the claims, vectors and plant transformed therewith, to identify those, if any, that encode BRZ1 and confer an increased size in plants transformed therewith.

Applicants contend that the state-of-the-art is high and that molecular biology techniques were worked out and included a high degree of automation owing to genome sequencing.

Applicants also contend that the skill in the art is quite high. Thus one of skill in the art is capable of screening through large numbers of random and site-directed mutants (page 13, 2nd and 3rd full paragraphs).

The Office concurs that the state-of-the-art is high and that there exists a certain amount of automation, but, the identification, isolation and testing of each putative non-exemplified sequence still has to be processed individually and produces undue trial and error experimentation.

Applicants contend that the effects of mutations in genes cannot be predicted with 100% accuracy but the working examples combined with sequence alignment provides some degree of predictability (page 13, 4th full paragraph).

The Office contends that the working examples do not provide guidance for determining which nucleic acids can be deleted, substituted or added and still encode a protein with the same activity as SEQ ID NO:6. Applicants are invited to submit a 1.132 declaration indicating the conserved domains of the proteins that are required for the biochemical function of the claimed invention.

Applicants contend that the breadth of the claims is such that one of skill in the art would not expect substantial variation under high stringency conditions and 80% identity (page 13, 5th full paragraph).

The Office contends that Applicants have not disclosed a biochemical function for the claimed invention. Without a stated biochemical function, one of skill in the art cannot determine, in part, which sequences are encompassed by Applicants' broadly claimed invention.

Applicants are invited to submit a 1.132 declaration indicating the conserved domains of the proteins that are required for the biochemical function of the claimed invention.

7. Claims 25 and 26 are allowable.

8. Claims 1-23 are not allowable.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart F. Baum whose telephone number is 571-272-0792. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 571-272-0804. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Stuart F. Baum Ph.D.
Patent Examiner
Art Unit 1638
August 31, 2004

AMY J. NELSON, PH.D
SUPERVISORY PATENT EXAMINER
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